

not be cleaved by GST P1-1, Telik scientists demonstrated that the non-cleavable analog was inactive, and therefore that cleavage is required for TLK286 activation and subsequent cancer cell killing. This result supports the premise that the selective activation of TLK286 within cancer cells contributes to the generally mild side effect profile and antitumor activity of TLK286 seen in clinical trials.

- **Enhanced antitumor activity of TLK286 in combination with oxaliplatin, carboplatin, doxorubicin, paclitaxel and docetaxel in human colorectal, ovarian, non-small cell lung and breast cancer cell lines (Abstract # 1722).** Human cancer cell lines were treated with TLK286 in combinations with several important chemotherapeutic drugs. The studies consistently demonstrated enhanced or synergistic cancer cell growth inhibition. For example, treatment of a colorectal cancer cell line with TLK286 and oxaliplatin resulted in a fifteen-fold increase in growth inhibition compared to the sum of either agent alone. These data, and the mild, non-overlapping toxicities seen in clinical trials of TLK286, suggest that combinations may be appropriate and provide scientific support for ongoing clinical trials using TLK286 in regimens with docetaxel, carboplatin and doxorubicin (Doxil®).
- **Sensitization of a human cancer cell line to paclitaxel following prolonged treatment with TLK286 (Abstract #LB123).** Following up on the combination studies, Telik scientists examined the effects of prolonged exposure of human ovarian cancer cells to TLK286. TLK286 exposure was associated with enhanced sensitivity of the cancer cells to taxanes, an important class of chemotherapeutic drugs.

44. On April 24, 2003, the Company issued a release entitled "Telik Announces First Quarter 2003 Financial Results." The release stated, in relevant part, as follows:

Key developments at Telik since the beginning of 2003 have included:

- The initiation of a Phase 3 registration trial of TELCYTA™ in ovarian cancer patients whose disease has progressed following platinum-based chemotherapy and one second-line treatment. The multinational trial, designated the **ASSIST-1 (Assessment of Survival In Solid Tumors-1)** trial, is designed to evaluate whether TELCYTA™ treatment reduces the risk of death, leading to an increase in survival, as compared to the control group treatments.

- The publication of new preclinical data that support the ongoing clinical development of TELCYTA™. These data elaborate on the proposed mechanism of activation and activity of TELCYTA™ and describe the use of TELCYTA™ in combination with standard chemotherapeutic drugs.

45. On Saturday, May 31, 2003, the Company made a presentation at the American Society of Clinical Oncology ("ASCO"), proclaiming that its in-progress follow-up trial on advanced lung-cancer patients treated with TELCYTA confirmed earlier data that the drug increased survival times. At ASCO, defendants explained that TELCYTA's Phase 2 trial involved non-small cell lung-cancer patients who had failed two or more previous therapies and who had life expectancies of 4-1/2 to 6-1/2 months. In an interview with *Dow Jones Newswires* at the ASCO meeting, Brown reported that of the 33 patients enrolled 81% were still alive. Other key findings presented included the following results:

- **"Ovarian cancer:** New interim clinical results *confirmed* the significant clinical activity reported in the previous Phase 2 clinical trial of TELCYTA in women with advanced ovarian cancer, and supported the ongoing Phase 3 trial in this potential indication."
- **"Non-small cell lung cancer:** Interim results from a second Phase 2 clinical trial in poor prognosis patients who have failed platinum-containing regimens *confirmed* the results reported in the prior Phase 2 clinical trial in non-small cell lung cancer, in which disease stabilization was associated with a median survival that was significantly improved over that expected for these patients."
- "In these clinical trials, as in the previous clinical trials, TELCYTA treatment was *well-tolerated, with most side effects mild and reversible.*" Defendants stated there were few "grade 1" and "grade 2" side effects and no "grade 3" or "grade 4" events experienced.
- Telik "plan[ed] to initiate a registration Phase 3 Trial of TELCYTA™ for the treatment of advanced non-small cell lung cancer."

46. On June 1, 2003, the Company issued a release entitled "Telik Announces Confirmatory Results from Second Phase 2 Trial of TELCYTA™ in Advanced Non-Small Cell Lung Cancer," which stated, in relevant part, as follows:

Telik, Inc. (Nasdaq: TELK) announced positive interim results from a second Phase 2 clinical trial of TELCYTA™ (TLK286) administered as a single agent in women with platinum refractory or resistant ovarian cancer, that confirm the previous results of a previous Phase 2 trial in this patient population. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

The interim results show a 17% objective response rate (three partial responses by RECIST criteria) and 56% overall disease stabilization rate in women with advanced, platinum refractory or resistant ovarian cancer. Responses were accompanied by clinical symptom improvement. Median duration of stable disease is greater than six months and ongoing. Median survival has not yet been reached. TELCYTA™ continues to be well-tolerated, with the most common adverse events categorized as Grade 1 or 2 (mild to moderate). Grade 3 adverse events were infrequent, and no Grade 4 adverse events were reported.

The interim analysis is based on 33 patients evaluable for survival and 18 patients evaluable for tumor response. All of the patients were either refractory or resistant to platinum, and 82% were resistant to paclitaxel and additional salvage therapies.

"These results confirm the clinical activity reported in the previous Phase 2 trial of TELCYTA™ in advanced ovarian cancer and support the ongoing Phase 3 registration trial of TELCYTA™ in the third-line ovarian cancer setting," said Gail L. Brown, M.D., senior vice president and chief medical officer. "The interim results of this trial are comparable with those of the first ovarian cancer trial at a similar stage. This is encouraging because, in our earlier Phase 2 trial, clinical responses correlated with improved overall median survival. The efficacy, favorable toxicity profile and non-overlapping toxicities reported with TELCYTA™ now observed over a wide range of patient drug exposure, facilitate its use both as a single agent and in combination regimens in less advanced patients."

"Further, we are pleased to report that the ovarian cancer patient in our earlier Phase 2 trial, whose complete response following TELCYTA™ treatment was first reported at the 2002 ASCO meeting, remains in complete remission and off all treatment for ovarian cancer," Dr. Brown said. "This durable, long-term complete response is particularly encouraging because her disease was refractory to platinum therapy."

In Phase 2 trials, TELCYTA™ has demonstrated clinical activity in breast, non-small cell lung and colorectal cancer, in addition to ovarian cancer. A high proportion of these tumors express GST P1-1, which activates TELCYTA™ within the tumor.

47. On June 2, 2003, the Company issued a release entitled “Telik’s TELCYTA™ (TLK286) Demonstrates Significant Clinical Activity in Advanced Metastatic Breast Cancer,” which stated, in relevant part, as follows:

Telik, Inc. announced positive interim results from the first Phase 2 study of TELCYTA™ (TLK286) in the treatment of women with advanced metastatic breast cancer. The data were presented at the annual meeting of the American Society of Clinical Oncology in Chicago.

There was a 15% objective response rate (one complete response and two partial responses by RECIST criteria), and a 35% overall disease stabilization rate in this poor prognosis patient group. Median duration of stable disease is greater than 4 months and ongoing. TELCYTA™ continues to be well-tolerated, with the most common adverse events in this trial categorized at Grade 1 or 2 (mild to moderate). There were few Grade 3 and no Grade 4 adverse events.

The interim analysis is based on 40 women with Stage IV metastatic breast cancer, 20 of whom were evaluable for tumor response at the time of interim analysis. All of the patients had failed two or more prior therapies including anthracyclines and taxanes. Most of the patients have disease that had metastasized to two or more organ systems.

“We have for the first time demonstrated responses to TELCYTA™ in advanced metastatic breast cancer, in women who have exhausted essentially all treatment alternatives,” said Gail L. Brown, M.D., senior vice president and chief medical officer. *“The interim results of this trial, including objective complete and partial responses, support further testing of TELCYTA™ in advanced breast cancer, a very difficult to treat cancer, as a single agent as well as in combination regimens in less advanced patients.”*

In Phase 2 trials, TELCYTA™ has demonstrated clinical activity in ovarian, non-small cell lung and colorectal cancer, in addition to breast cancer. A high proportion of these tumors express GST P1-1, which activates TELCYTA™ within the tumor.

48. Based on the highly positive May 31, 2003 – June 2, 2003 statements above, Telik shares increased \$1.44, or 9.5%, to over \$16 per share on June 2, 2003.

49. On June 30, 2003, the Company held an earnings conference call with investors and financial analysts. During this call, Defendant Wick responded to questions from several analysts, in relevant part, as follows:

George Farmer, Fortis Securities: Can you give an update on median survival of first ovarian cancer phase 2 trial?

Michael Wick, Telik CEO: The last public update we gave was in Nov 2002 at the ORTC meeting, I think it was 71 weeks. The data continued very strong, we don't really update it because it requires calling each patient to find out if they're alive or dead. We're focused on the phase 3 trials now. Sometime along the line we'll give final data on that. But it continues strong.

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Joel Sendek, Lazard Freres: And what difference from the control arm are you looking for?

Michael Wick, Telik CEO: **This is an event driven trial, and the event is death. The trial has a 98 percent probability to show a 25% reduction in the risk of death. That translates into approximately a 40% increase in median survival over the control arm. That's really a translation of the primary math. We surpassed that by quite a bit in both ovarian cancer trials.**

50. On July 30, 2002, the Company issued a press release entitled "Telik Announces Second Quarter 2003 Financial Results," which stated, in relevant part, as follows:

At the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2003, Telik reported positive new interim results from Phase 2 clinical trials of TELCYTA™ in ovarian, non-small cell lung and breast cancer. Key findings included:

**Ovarian cancer:** New interim clinical results confirmed the significant clinical activity reported in the previous Phase 2 clinical trial of TELCYTA™ in women with advanced ovarian cancer, and support the ongoing Phase 3 trial in this potential indication.

**Non-small cell lung cancer:** Interim results from a second Phase 2 clinical trial in poor prognosis patients who have failed platinum-containing regimens confirmed the results reported in the prior Phase 2 clinical trial in non-small cell lung cancer, in which disease stabilization



was associated with a median survival that was significantly improved over that expected for these patients.

\* \* \*

**In these clinical trials, as in the previous clinical trials, TELCYTA™ treatment was well-tolerated, with most side effects mild and reversible.**

51. During the Company's earning conference call held on July 30, 2003, following the press release that day, Wick stated the "strict, independently verified response criteria" being used in the ovarian cancer arm of the studies were typically reserved only for use in Phase III trials, but that they were being employed in this Phase II trial as part of the Company's "strategy of *reducing risks going forward by conducting Phase 2 trials to Phase 3 standards.*" Defendants also stated that the Company's quarterly cash burn would increase to between \$55 and \$60 million per quarter when the Phase III ovarian study began.

52. On August 14, 2003, the Company issued a release entitled "Telik Announces Positive Follow-Up Results from Phase 2 Trial of TELCYTA™ in Advanced Non-Small Cell Lung Cancer," which purportedly confirmed the efficacy data presented at the May 2003 ASCO meeting. Therein, the Company, in relevant part, stated the following:

Telik, Inc. (Nasdaq: TELK) reported positive follow-up data from a Phase 2 clinical trial of TELCYTA™ (TLK286) in patients with non-small cell lung cancer whose disease progressed following platinum-containing regimens. The data were reported at the Tenth World Conference on Lung Cancer in Vancouver, British Columbia.

Patients enrolled in this trial received TELCYTA™ as second- or third-line treatment for advanced non-small cell lung cancer. An 11% objective response rate was observed in the 19 patients evaluable for efficacy at the time of analysis. The overall disease stabilization rate was 69%. Median survival has not yet been reached. TELCYTA™ continues to be well tolerated, with the most common adverse events categorized as Grade 1 or 2 (mild to moderate).

"These maturing results further confirm the clinical activity of TELCYTA™ that has been reported in non-small cell lung cancer, including earlier data from this trial presented at the American Society of Clinical Oncology meeting in June, and data

from a previous Phase 2 trial in non-small cell lung cancer,” said Gail L. Brown, M.D., senior vice president and chief medical officer. “We look forward to the initiation of the TELCYTA™ Phase 3 registration trial in non-small cell lung cancer later this year.”

In Phase 2 trials, TELCYTA™ has demonstrated clinical activity in ovarian, breast and colorectal cancer, in addition to non-small cell lung cancer. A high proportion of these tumors express GST P1-1, which activates TELCYTA™ within the tumor. A Phase 3 registration trial of TELCYTA™ in women with advance ovarian cancer is in progress, in addition to ongoing trials evaluating TELCYTA™ in combination with standard chemotherapies.

53. On September 3, 2003, the Company issued a press release entitled “Telik Announces FDA Fast Track Designation for TELCYTA™.” Therein, the Company, in relevant part, stated the following:

Telik, Inc. (Nasdaq: TELK) announced that the U.S. Food and Drug Administration has granted Fast Track designation for TELCYTA™ (TLK286) for third line therapy in patients with platinum refractory or resistant ovarian cancer.

“Fast Track designation is a recognition by the FDJA of the serious unmet medical need faced by women with platinum refractory or resistant ovarian cancer, and the potential of TELCYTA™ to address that need,” said Gail L. Brown, M.D., senior vice president and chief medical officer. A randomized Phase 3 registration clinical trial with TELCYTA™ is in progress for third line therapy in patients with platinum refractory or resistant ovarian cancer.

**Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.**

54. On October 1, 2003, Telik announced the successful completion of FDA Special Protocol Assessment review for TELCYTA for the treatment of lung cancer in the ASSIST-2 trial which would compare TELCYTA’s performance to that of Iressa, a similar cancer-treating drug. Therein, the Company, in relevant part, stated the following:

Telik, Inc. (Nasdaq: TELK) announced that the Phase 3 protocol for TELCYTA™ (TLK286) in non-small cell lung cancer (NSCLC) has successfully completed Special Protocol Assessment (SPA) review by the U.S. Food and Drug Administration.

The trial, designated **ASSIST-2** (Assessment of Survival In Solid Tumors-2), will enroll approximately 500 patients with platinum refractory or resistant NSCLC who will be randomized to receive either TELCYTA™ or Iressa® (gefitinib) for the third-line treatment of NSCLC. The study is designed to evaluate whether TELCYTA™ treatment leads to an increase in survival as compared to the control treatment. The first Phase 3 TELCYTA™ protocol, for the ongoing **ASSIST-1** trial of TELCYTA™ in women with platinum refractory or resistance ovarian cancer, previously underwent successful SPA review.

55. On October 29, 2003, the Company issued a press release entitled "Telik Announces Third Quarter 2003 Financial Results," which stated, in relevant part, as follows:

- The Phase 3 clinical trial protocol for TELCYTA™ in advanced non-small cell lung cancer (NSCLC) has successfully completed Special Protocol Assessment (SPA) review by the U.S. Food and Drug Administration. The protocol for the ongoing Phase 3 TELCYTA™ trial in platinum refractory or resistant ovarian cancer previously underwent successful SPA review.
- Telik received FDA Fast Track designation for TELCYTA™ for third-line treatment in patients with platinum refractory or resistant ovarian cancer.
- At the Tenth World Conference on Lung Cancer, Telik reported maturing results from a Phase 2 trial of TELCYTA™ in advanced non-small cell lung cancer, demonstrating an 11% objective response rate and 69% overall disease stabilization rate.
- Telik reported interim data from three Phase 1-2a clinical trials in which TELCYTA™ was used in combination with standard chemotherapy drugs. **Results indicate that the combinations were well tolerated at all doses tested.** In the carboplatin combination trial in heavily pretreated, third-line or greater patients who had failed a platinum-containing regimen, five of eight evaluable patients (63%) had objective tumor responses by the RECIST criteria, including one complete response, and an 88% overall disease stabilization rate was observed. In the docetaxel combination trial in second and third-line non-small cell lung cancer patients, three of 14 evaluable patients (21%) who received full doses of TELCYTA™ and docetaxel had objective tumor responses by the RECIST criteria, and the overall disease stabilization rate was 64%. In combination with Doxil®, the combination resulted in a 33% objective response rate by the RECIST criteria and 100% disease stabilization rate among the three evaluable ovarian cancer patients treated with the highest dose of each drug.



56. Also on October 29, 2003, the Company issued a press release entitled “Telik Announced Proposed Equity Offering.” Therein, the Company, in relevant part, stated as follows:

Telik, Inc. (Nasdaq: TELK) announced plans to offer 6,000,000 shares of common stock in an underwritten public offering under its existing shelf registration statement. Five million of the shares are expected to be offered by the company, and 1,000,000 shares are expected to be offered by a corporate selling stockholder. In addition, the underwriters will have an option to purchase from the company up to an additional 900,000 shares to cover over- allotments, if any.

57. The prospectus filed on November 6, 2003, in connection with the 2003 Offering also contained the following false and misleading statements:

- Defendants’ statement that TELCYTA’s ability to “bind[] to GST P1-1 inside a cancer cell” caused “a chemical reaction [to] occur[], releasing fragments of TELCYTA *that cause[d] programmed cancer cell death, or apoptosis*,” was false and misleading because it concealed that an unacceptably high level of side effects had been experienced during the Phase II testing of TELCYTA;
- Defendants’ statement that Telik had “initiated a Phase 3 registration trial of TELCYTA for the treatment of ovarian cancer in March 2003” was false and misleading as the ASSIST-1 study underway was not “*adequate and well-controlled*” and thus its results would not be accepted by the FDA as “*substantial evidence*” of TELCYTA’s efficacy;
- Defendants’ statement that “[r]esults from . . . trials [evaluating more than 400 cancer patients in 12 clinical trials] indicat[ing] that TELCYTA [was] generally well tolerated, with mostly mild to moderate side effects” was false and misleading because it concealed that subjects in the Phase 2 testing had experienced an unacceptably high level of side effects;
- Defendants’ statement that in “June 2003, at the American Society of Clinical Oncology annual meeting, [the Company] announced positive interim results from the multimember Phase 2 trials of TELCYTA in ovarian, non-small cell lung . . . cancer,” with TELCYTA “demonstrate[ing] significant single agent antitumor activity, including multiple objective tumor responses and prolongation of expected survival in patients who were unresponsive to standard treatments” in the ovarian cancer trial, was false and misleading because it concealed that subjects in the Phase II testing had experienced an unacceptably high level of side effects;

- Defendants' statement that the Company's "strategy" was to "develop product candidates with a clear path to regulatory approval and the potential to show *early evidence of clinical efficacy*," allowing Telik to "reduce the risk inherent in drug discovery and accelerate the commercialization of [its] drug candidates," was false and misleading as it concealed that subjects in the Phase 2 testing had experienced an unacceptably high level of side effects and that the ASSIST-1 trial then underway was not being conducted in an "adequate and well controlled" fashion, as would be required to be acceptable to the FDA.

58. On December 2, 2003, the Company issued a press release entitled "Telik Announced FDA Fast Track Designation for TELCYTATM for Non-Small Cell Lung Cancer." Therein, the Company, in relevant part, stated as follows:

Telik, Inc. (Nasdaq: TELK) announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for TELCYTATM (TLK286) for third line therapy for locally advanced or metastatic non-small cell lung cancer. The FDA previously granted Fast Track designation for TELCYTATM for third line therapy in patients with platinum refractory or resistant ovarian cancer.

**Fast Track programs are designed to facilitate the development and expedite the review of new drugs that *demonstrate the potential* to treat serious or life-threatening conditions and address unmet medical needs.**

59. On February 19, 2004, the Company issued a press release entitled "Telik Announces Fourth Quarter and Year-End 2003 Financial Results," which stated, in relevant part, as follows:

#### **TELCYTA**

- Telik reported positive, confirmatory results from additional Phase 2 studies of TELCYTA™ administered as a single agent in ovarian and non-small cell lung cancer at the American Society of Clinical Oncology meeting in June.
- The Phase 3 registration trial of TELCYTA™ in ovarian cancer was initiated. The trial is designed to enroll approximately 440 women with platinum refractory or resistant ovarian cancer who have also failed treatment with one of the approved second line agents.
- A Phase 3 registration trial of TELCYTA™ in platinum resistant non-small cell lung cancer was announced and is scheduled to begin in the current quarter.

- The protocols for the TELCYTA™ Phase 3 registration trials were reviewed by the FDA under Special Protocol Assessments, and the FDA granted Fast Track status for TELCYTA™ for the treatment of ovarian and non-small cell lung cancer in the third line setting.
- Positive interim clinical results were reported using TELCYTA™ in combination treatment regimens with carboplatin, Taxotere® and Doxil®, drugs that are used in current front line and second line chemotherapy.

60. Also on February 19, 2004, the Company held an earnings conference call with financial analysts and investors. During this call, certain Individual Defendants, in relevant part, stated the following:

MICHAEL WICK, CHAIRMAN AND CEO, Telik, INC.: Thanks, Carol. 2003 was a year of significant value creation at Telik, as we initiated the Phase III registration trial of TELCYTA in ovarian cancer and we prepare for the initiation of a Phase III trial in non-small cell lung cancer. We also presented positive interim data from the Phase II trials of TELCYTA in combination with carboplatin, Taxotere, and Doxil, which lays the foundation for advancing TELCYTA to the second and front line setting. In addition to the progress made in the TELCYTA development program, we continue to advance our second cancer compound, Telintra.

**At the American Society of Hematology meeting, we reported positive clinical data for Telintra, or TLK199, which supports further clinical development. The clinical results for TELCYTA and Telintra provide multiple opportunities for Telik in 2004, which I'll now discuss.**

First, we will review our progress and plans for TELCYTA, our lead product candidate. ...

Following this rationale, we've constructed TELCYTA to be a small molecule that is administered to cancer patients in an inactive form. It can be processed within cancer cells by an enzyme called GSTP11, that has shown to be expressed in higher levels in ovarian, lung, breast, colorectal, pancreatic, lymphoma, as well as in other cancers, than in normal cells. The targeted activation of TELCYTA results in the release of highly reactive fragments that rapidly interfere with RNA, DNA, and proteins, overwhelming the ability of the cancer cell to escape. Furthermore, a safety profile consistent with targeted activation within cancer cells is observed with a relatively sparing of normal cells.

**In our TELCYTA development program, we have attempted to reduce development risks by conducting nine successful Phase II trials in four indications. Our strategy was to measure TELCYTA against a high hurdle in order to estimate its realistic potential early in the development process. In addition, we applied several traditional principles of cancer drug development, including testing TELCYTA as a single agent, so that we knew that whatever positive effects observed could be attributed to TELCYTA, and whatever negative effects observed were also due to TELCYTA, challenging TELCYTA early by treating more refractory patients with worse prognoses than we expected to treat in our Phase III trials, and showing safety and efficacy in more advanced cancer patients is always more difficult for any cancer drug; confirming the actually we observed in our first Phase II trial by repeating the Phase II trials in lung and ovarian cancer; by providing visibility into the potential survival benefit caused by TELCYTA, although in a non-randomized setting.**

**In addition to adhering to these traditional principles, we also used the more stringent resist criteria to assess tumor response. This is the same criteria that we are now employing in our Phase III trials -- resist, as you know, requires, for example, radiologic confirmation of tumor response by independent radiologic exam.**

Finally, for both Phase III trials, we have received FDA fast track designation and completed a special protocol assessment process.

**TELCYTA is very well tolerated across all of our trials, consistent with the proposed mechanism of activation within cancer cells. The principle toxicities are mild to moderate nausea and vomiting, which is well controlled with standard antiemetics not seen as often severe, treatment-limiting organ toxicities common to many cancer drugs. We observed numerous objective responses including responses in bulky tumors as well as long-term disease stabilization and longer patient survival than would be expected in these advanced populations. These results provide the foundation for our Phase III registration trials.**

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Demonstrating the safety and clinical activity of TELCYTA as a single agent was, of course, a very important objective. We also are advancing the TELCYTA development program by conducting combination Phase II trials in order to move TELCYTA into earlier- stage treatment regimen. Under review - the principles of combination therapy. ...

At the EORTC meeting in Boston in November, we presented what I believe is the most significant TELCYTA data since ASCO of 2002 -- positive preliminary results from combination [inaudible] for drugs that

represent the mainstay of chemotherapy for solid tumors including platinum, [taxine] and [anthrocycle]. In [inaudible] of the three trials reported, the patients enrolled in the combination TELCYTA/carboplatin trials, who are ovarian cancer patients for refractory or resistant to carboplatin. In these patients, the expected response rate to platinum approaches zero, while the response rate to TELCYTA, based on our Phase II trials, will be expected to be in the range of 15% to 19%. In the combination trial, reportedly 63% objective response rate, including a durable complete response and an 88% overall disease stabilization rate. We saw no unanticipated toxicity, now continuing enrollment and dose escalation of TELCYTA.

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To summarize our progress with TELCYTA, the past year has seen the combination of single-agent activity and, second, the Phase II trials in ovarian and non-small-cell lung cancer, the demonstration of activity in breast cancer, demonstration of TELCYTA activity in combination with three major classes of chemotherapeutic drugs. The Phase III trial on ovarian cancer is well underway. We remain on track to begin the Phase III study of non-small-cell lung cancer before the end of March. Which we now, in the end of 2004, we intend to initiate several additional trials using TELCYTA in combination regimen in the front line and second line settings; trials that provide near-term visibility to the full clinical and market potential of TELCYTA.

These advances, we believe, have significantly increased the value of TELCYTA for Telik and for potential partnerships outside the U.S., which we continue to pursue. Also, looking ahead, several mechanistic abstracts described in the underlying mechanism of synergy of TELCYTA as well as explain the synergy with standard agents have been accepted by the American Association of Cancer Research meeting at the end of March, and we expect to present, as mentioned earlier, additional TELCYTA combination data at ASCO in June.

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CYNTHIA BUTIHA, COO AND CFO, Telik, INC.: ... As Mike has just described, we have set very aggressive goals for Telik in 2004 based on the compelling clinical data we have reported over the past year. These goals include completing enrollment in the two Phase III registration trials for TELCYTA in ovarian and non-small-cell lung cancer; completing and reporting data on the Phase II combination trials of TELCYTA with carboplatin, Taxotere, and Doxil; completing the single-agent breast cancer trial reporting data later this year; initiating a number of new pilots in randomized combination TELCYTA studies including a front line trial



with platinum and non-small-cell lung cancer as well as additional combination trials in ovarian and non-small-cell lung cancer in either the front line or second line study; manufacturing the registration batches of TELCYTA in preparation for the CMC section of our TELCYTA NBA; completing the Telintra Phase I-IIa trial in MDS; and advancing the development of an oral formulation of Telintra including pre-clinical IND-enabling studies for a potential INDx filing in the first half of 2005.

**The achievement of these goals with TELCYTA and Telintra will provide a strong foundation for continued growth and stockholder value for Telik, and balancing these goals with our financial resources, we anticipate committing proportionately less resources to our pre-clinical pipeline relative to the clinical opportunities in 2004. Based on the significantly expanded clinical and development programs for TELCYTA and Telintra, and the many activities that support our clinical programs including manufacturing and the beginning of NBA filing preparations, we anticipate total operating expenses in 2004 will be approximately \$90m to \$95m. Cash burn is estimated to be in the \$85m to \$90m range with a delta being noncash expenses and interest income. We are not guiding to any revenue from potential partnerships although, of course, there is that potential there.**

Consistent with our focus on clinical trials and related support, we anticipate that approximately 85% of our operating expenses will be in research and development and 15% in G&A. Further, as we add new trials and accelerate NDA-related activities, we expect expenses to ramp up over the year with approximately 45% of operating expenses in the first half of 2004 in the balance of the second half. **The plan we describe reflects our enthusiasm about the potential for TELCYTA and Telintra and our belief in them as near-term growth drivers for the company. We have demonstrated the clinical activity of TELCYTA in refractory and resistant cancer, now moving rapidly into the important studies of front line and second line treatment with combination regimen.**

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JAMES BIRCHENOUGH: ... one final question on TELCYTA should we expect at some point this year an interim look at the data for purposes of seeking accelerated approval in ovarian?

MICHAEL WICK: Well, you know, we designed this trial with all the bells and whistles. You know what's very well. You know, I think we've given the same guidance we've given right along -- we're committed to finishing this trial. We've built in every opportunity to have success. We will communicate with Wall Street if there are any --

**you know -- if the independent data monitoring committee makes any substantive recommendations**, you know, there can be lots of them along the way. You know, if the assumptions on the trial were not borne out that we agreed 'to, we might have to adjust our trial. **We certainly don't expect -- nor have we seen any evidence of safety concerns for TELCYTA, which is typically an issue. But insofar as any interim looks don't change our original guidance, we won't communicate them. Insofar as they do, we will.** Cindy, do you have any comments on that?

CYNTHIA BUTITTA: No, that's correct.

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MICHELLE PARK, ANALYST, CREDIT SU[SSE FIRST BOSTON: Most of my questions have been answered. I was wondering if you are disclosing the number of patients that have been enrolled thus far in the ovarian cancer study?

CYNTHIA BUTITTA: No, we're not providing that guidance.

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GEORGE FARMER: It has, okay. Finally, in the Phase III lung trial that's about to get underway, can you talk about any exclusion or inclusion criteria?

MICHAEL WICK: I think, no, without getting in too detailed -- I mean -- typically, these patients -- it's our belief, as has been true in our Phase II studies, and the FDA is very clear about this -- that the population you study should reflect the population that you intend, ultimately, to market to. ...

GEORGE FARMER: But I would imagine it's very tempting, given the variable response rate of Iressa in different segments of the lung cancer population, and given that there is very little for treatment of third line lung cancer, anyway, to think about how you could design a trial where you could really show an enhanced effect of TELCYTA in that setting.

MICHAEL WICK: That's true, but one has to, you know, not be too clever by half, okay? That base is a straightforward trial. You know, we have to make it, we have to be sensitive to the patient's need. For example, we will allow them to bail other EGFR inhibitors simply because the main drivers, we believe, with the FDA are the improved platinum, the improved Taxoteres, or whatever else they fail along the way, that would be acceptable. For example, we certainly will not attempt to enrich

our population in any of the histiotypes. We believe that we can provide enough advantage to TELCYTA by simply following the normal distribution of histiotype that you can look up in any textbook. We will, for example, if patients, in addition to platinum, had received an EGFR inhibitor, we will allow that. Again, another one, although is -- it's an interesting concept you're raising, you know, as one deals with the FDA process and the FDA and Dr. Brown, here, we do this pretty straight.

61. On April 29, 2004, the Company issued a press release entitled "Telik Announces First Quarter 2004 Financial Results," which stated, in relevant part, as follows:

- The ASSIST-2 trial, a multi-national Phase 3 registration trial of TELCYTA in non-small cell lung cancer (NSCLC), was initiated as planned. The trial is expected to enroll approximately 520 patients who are being randomized to TELCYTA treatment or to a control group receiving Iressa®, the approved third-line treatment for NSCLC.
- A Phase 1-2a clinical trial was initiated to evaluate the combination of TELCYTA and cisplatin in NSCLC patients who have not previously received chemotherapy.
- At the American Association of Cancer Research (AACR) 94<sup>th</sup> annual meeting, preclinical data were presented demonstrating that TELCYTA demonstrated synergy, or enhanced inhibition of cancer cell growth, in combination with a number of chemotherapeutic drugs, including platinum, taxanes, anthracyclines and EGFR targeted drugs.
- Also at the AACR meeting, data were reported showing that, in preclinical models, TELCYTA is non-cross resistant with taxanes, and that TELCYTA is capable of re-sensitizing cancer cells to taxanes after resistance is established.

62. Also on April 29, 2004, the Company held an earnings conference call with financial analysts and investors. During this call, the Defendants Wick and Butitta, in relevant part, stated the following:

DR. MICHAEL WICK, CHAIRMAN & CEO, Telik, INC.: ...

Phase 3 trials follow the comprehensive successful Phase 2 clinical development program, now having treated hundreds of patients with thousands of doses, including two confirmatory single-agent trials, each in ovarian and non-small cell lung cancer, as well as trials in breast and colorectal cancer. **Across these trials, TELCYTA has demonstrated significant anti-tumor activity, continued outstanding tolerability, and a favorable impact on survival, compared to expected, in those very advanced patients. We have previously reported data for these trials**

at ASCO and other scientific meetings, and now are in the process of publishing them in peer review journals.

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The advantage to earlier stage patients has always been part of our clinical development program, but the very strong data has allowed us to accelerate that part of the program with the attendant acceleration of market opportunity and revenue. We will, of course, be certain that these trials do not compromise the execution of the current Phase 3 trial. Given (indiscernible) the design, we believe this trial could be advantageous also to Telik. and an NDA filing next year. There are many advantages to an accelerated broader development program for TELCYTA that lead to a better regulatory and commercial package. The results from this trial will strengthen the case for favorable reimbursement. And together with the single-agent trials in third-line allow for the most efficient growth for TELCYTA in this clinical indication.

CYNTHIA BUTITTA, COO & CFO, Telik, NC.: Thanks, Mike. ... the opportunity for continued growth and value for our shareholders through the development of TELCYTA and Telintra is very significant. Since the last call we have initiated, as planned, the Phase 3 registration trials for single-agent TELCYTA in non-small cell lung cancer, and we also initiated a front-line non-small cell lung cancer trial using TELCYTA in combination with Cisplatin. Our guidance on timing for the Phase 3 trials remains unchanged. We have over 150 sites activated in the ovarian trial and we expect enrollment to be completed later this year. We also expect to complete accrual in the lung cancer trial within the year. Since both trials are event-driven, the timing for having results is not precisely predictable. **We design these trials with interim looks to provide opportunities for accelerated approval, although we are prepared to complete the trials and anticipate filing the NDA in the second half of '05.**

As Mike has described, we expect to open new combination studies with TELCYTA, including randomized, Phase 3 trial evaluating TELCYTA plus Carboplatin versus Topotecan in ovarian cancer patients as a second-line setting by midyear. For the Telintra program, we expect to complete the ongoing trial in MDS patients and to advance the oral formulation of Telintra toward an IND filing in the first half of '05.

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JOEL SENDEK: Okay. You talked about the interim looks built into the other studies. Have you told us when you might -- when those interim looks are, if you will comment on that?

DR. MICHAEL WICK: It is very important for us to keeping the pristine (technical difficulty) nature of those trials in tact and their scientific integrity. **We think it's important to offer our investors, or shareholders, every opportunity to participate in this. So this is a state-of-the-art trial, with all in scale points out the bells and whistles. They include interim looks, independent data safety monitoring boards. Typically, these are based on fractions of events occurring. As you know, the endpoints are response rates, TTPN, and death, are the typical issues. And Cindy said earlier, we began the trial, but we'll only communicate with the street if any of those interim looks change in a material way our guidance for that trial, either in terms of size, of timing, or that's finished. Okay, and so far, none of those have occurred.**

63. On August 5, 2004, the Company issued a press release entitled "Telik Announces Second Quarter 2004 Financial Results," which stated, in relevant part, as follows:

**American Society of Clinical Oncology (ASCO) Annual Meeting:** At the ASCO meeting in June, Telik reported positive results from three Phase 2 trials of TELCYTA used in combination with standard chemotherapy: TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer; TELCYTA plus liposomal doxorubicin in platinum refractory or resistant ovarian cancer; and TELCYTA plus docetaxel in platinum resistant NSCLC.

**Phase 2 TELCYTA trial in front-line NSCLC:** Telik announced the initiation of a Phase 2 trial to evaluate TELCYTA in combination with carboplatin and paclitaxel in the front-line treatment of Stage IIIb or IV NSCLC. The trial is being conducted at teaching affiliates of the Harvard Medical School including the Dana-Farber Cancer Institute, Massachusetts General Hospital and Beth Israel Deaconess Medical Center. Thomas Lynch, M.D., Medical Director, Center for Thoracic Cancers, Massachusetts General Hospital and Associate Professor of Medicine, Harvard Medical School, is Principal Investigator of the study.

64. On September 8, 2004, Telik officers presented at the Thomas Weisel Healthcare Tailwinds 2004 Conference in Boston, on September 14, 2004, at the Bear Stearns' Healthcare



Conference in New York City, and on September 28, 2004, at UBS's Global Life Sciences Conference in New York City. The events were later webcast from Telik's website.

65. On November 4, 2004, the Company issued a press release entitled "Telik Announces Third Quarter 2004 Financial Results," which stated, in relevant part, as follows:

**10<sup>th</sup> Biennial International Gynecologic Cancer Society (IGCS) Meetings:** Telik reported data from two positive Phase 2 clinical trials of TELCYTA administered in combination with standard chemotherapy in platinum refractory or resistant ovarian cancer. The results included the following statements:

- **TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer:** a total of 53 patients have been enrolled in the trial, 27 of whom were evaluable for efficacy at the time of analysis. The objective response rate by RECIST is 54%, including 4 durable complete responses and 10 partial responses that have been independently reviewed. Objective responses were observed at all participating institutions including the Massachusetts General Hospital, Dana-Farber Cancer Institute and University of Texas M.D. Anderson Cancer Center. Based on these data, Telik plans to initiate the ASSIST-3 Phase 3 trial, to evaluate the combination of TELCYTA plus carboplatin versus Doxil in the second line treatment of platinum refractory or resistant ovarian cancer.
- **TELCYTA plus Doxil in platinum refractory or resistant ovarian cancer:** a total of 51 patients have been enrolled in the trial, including 12 treated in a separate dose-escalation phase. At the time of analysis, 19 patients in Phase 2 were evaluable for efficacy. The objective response rate by RECIST is 42%, with eight partial responses that have been independently reviewed.

66. On December 29, 2004, the Company announced that enrollment in ASSIST-1 was complete and that enrollment in ASSIST-3 was commencing. That day, the Company issued a press release entitled "Telik Completes Enrollment in ASSIST-1, Initiates ASSIST-3 and Reviews Status of ASSIST-2 Clinical Trials." Therein, the Company, in relevant part, stated the following:

Telik, Inc. (Nasdaq: TELK) announced the completion of enrollment for the ASSIST-1 clinical trial of TELCYTATM (TLK286), and the initiation of a new randomized Phase 3 trial of TELCYTA called ASSIST-3, in second line platinum refractory or resistant ovarian cancer.

ASSIST-1 is a randomized Phase 3 study designed to enroll 440 women in the third line treatment of platinum refractory or resistant ovarian cancer. Enrollment is complete.

ASSIST-3 is a randomized Phase 3 study designed to enroll 244 women with 122 to be treated with the combination of TELCYTA plus carboplatin, and 122 to be treated with Doxil®. The trial endpoints are objective response rate, progression-free survival and overall survival. The study is based on a positive multicenter Phase 2 study of the combination of TELCYTA plus carboplatin in platinum refractory or resistant ovarian cancer, first presented at the annual meeting of the American Society of Clinical Oncology earlier this year and later updated at the Tenth Biennial International Gynecologic Cancer Society meeting. The initial participating institutions are the Harvard Affiliated Hospitals including the Massachusetts General Hospital, Dana-Farber Cancer Institute, Brigham and Women's Hospital, and Beth Israel Deaconess Medical Center.

ASSIST-2 is a randomized Phase 3 study designed to enroll 520 patients in the third line treatment of platinum resistant non-small cell lung cancer. Enrollment continues as planned and the company anticipates completion of enrollment in the first quarter of 2005.

67. On January 24, 2005, the Company issued a press release entitled "Telik Announces Proposed Public Offering of Common Stock." Therein, the Company, in relevant part, stated as follows:

Telik, Inc. (Nasdaq: TELK) today announced that it plans to file a prospectus supplement with the Securities and Exchange Commission related to an underwritten offering of 5,000,000 shares of its common stock under an existing shelf registration statement. In connection with the offering, Telik expects to grant the underwriters a 30-day option to purchase up to 750,000 additional shares to cover over-allotments, if any.

UBS Investment Bank is acting as the sole book-running manager in this offering. J.P. Morgan Securities Inc. and Lehman Brothers are acting as co-managers.

68. In connection with the Company's January 2005 Offering, the Company filed a Prospectus (the "Prospectus") on January 28, 2005. That Prospectus indicated that the Company now sought to sell 7 million shares of Telik stock for sale to the public at \$18.75 per share, with